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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 09/846,512 | 05/01/2001 | Rachel Meyers | 10448-046002 / MPI2000-18 | 5523 |
| 26161 | 7590 | 10/14/2003 | EXAMINER | |
| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | YU, MISOOK | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1642 | (9) | |

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/846,512 | MEYERS ET AL. |
| | Examiner | Art Unit |
| | MISOOK YU, Ph.D. | 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 54-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 54-68 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: See *Continuation Sheet*.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Claims 19, 54-68 are pending and examined on merits.

Drawings

The drawings were received on March 20, 2003. These drawings are acceptable.

Specification

The objection of disclosure is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment as well as the persuasive argument.

The newly submitted Claims 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the interpretation step linking the active steps of the claims to the purpose stated in the preamble of the claims. While all of the technical details of a method need not be recited, the claims should include

enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

The rejection of claims rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement is **withdrawn** because applicant argument is persuasive.

Claims 19, 58, 63, and 64 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 19, 58, 63, and 64 are interpreted as drawn to method comprising contacting a cell expressing SEQ ID NO:12 with a compound, detecting hydrolysis of said compound, and concluding said compound either binds or interact SEQ ID NO:12 when hydrolysis of said compound is detected. Underwood et al (see art rejection below) or Scott et al (2001, *Nature Genetics*, vol. 27, pages 59-63) teach that a cell (a live organism) has many proteases whose function, i.e. hydrolysis of peptide bond, are similar to instant SEQ ID NO:12. The specification does not teach how to determine whether hydrolysis of a compound is caused by SEQ ID NO:12 or any other proteases of a cell. Note other proteases of a cell listed in the paragraph bridging

left and right columns of page 338 of Underwood et al, or the proteases produced by the alternate splicing forms disclosed at page 59 of Scott et al. In summary, neither the art nor the specification teaches an assay capable of concluding that hydrolysis of a compound is occurred by SEQ ID NO:12.

The new claim 64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 64 requires use of "a substrate" of SEQ ID NO:12 protease. The specification does not describe the chemical structure of a substrate of SEQ ID NO:12. Further, Underwood et al (see art rejection below) teach that SEQ ID NO:12 substrates have not been identified.

Priority

The Applicant's claim for domestic priority i.e. a CIP of Appl. No. 09/633,300, filed 08/08/2000, which claims the benefit of US Provisional Appl. No. 60/200,621 filed 04/28/2000 is acknowledged. However, the parent applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 54-68 of this application. Claims 54-68 require SEQ ID NO:12 protein. However, neither the Non-provisional Application nor the Provisional Application discloses SEQ ID NO:12. Note the protein sequence disclosed in the parent cases and instant SEQ ID NO:12 are not same. SEQ ID NO:2 of the parent cases has 453 aa but instant SEQ ID NO:12 is 454

aa protein. Note attached SEQ ID NO:2 of the parent cases is missing Alanine. ***Claim***

Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 19, 54-56, 59, and 68 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Underwood et al, *Biochim Biophys Acta*. 2000 Nov 15;1502(3):337-50.

The instant claims have two part active steps, i.e. contacting SEQ ID NO:12 protein with a compound and determine whether the compound binds said protein. Underwood et al discloses a protein identical to instant SEQ ID NO:12 (note Fig. 4, also note the attached sequence alignment). The instant claims read on the immunohistochemistry assay of the prior art at page 340 and Fig. 7. This rejection affects all dependent claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone

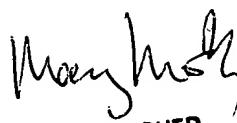
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number for the organization where this application or proceeding is assigned is (703)
872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
October 9, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600